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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 50D2012035 | (X3) Date Survey Completed 05/25/2023 |
| Name of Provider or Supplier Kittitas County Public Hospital District 2 | Street Address, City, State 111 Pine St, Cle Elum, WA | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on competency review, and interview with the Laboratory Director (LD), the Laboratory Director failed to ensure competency assessment for two of two Technical Consultants (TC). Findings include: 1. Record review of TC #1 showed no annual TC competency assessment for the year 2022. 2. Record review of TC #2 showed no TC competency for the years 2021 and 2022. 3. Interview with LD on 05/25/2025 at 12:00 PM confirmed that the laboratory failed to assess TC competencies.</p> |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review and interview with the Laboratory Director (LD), the laboratory failed to review ungraded American Proficiency Institute (API) PT for the second event for the year 2022. Findings include: 1. Record review of API PT showed that the laboratory failed to review ungraded PT results for second event for the year 2022 for the analyte Carbon Dioxide (CO2). 2. Record review of PT second event for the year 2022 showed one of five CO2 results were out of the acceptable limits. 3. Interview with LD confirmed on 05/25/2023 at 12:00 PM</p> |

that the ungraded CO2 PT analytes were not reviewed or evaluated. 4. The laboratory performs 1500 Chemistry tests annually.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on verification record review and interview with the Laboratory Director (LD), the laboratory failed to verify the establishment and verification performance specifications for the two of two i-STAT analyzer(s). Findings include: 1. Record review showed no documentation of the establishment and verification of the i-STAT analyzer(s) to include accuracy, precision, reportable range, and manufacturer's reference intervals (normal values). 2. Interview with the Laboratory Director on 05/25 /2023 at 12:00 PM confirmed that the laboratory failed to verify the establishment and verification of the i-STAT analyzer(s). 3. The laboratory performs a combined 1860 Chemistry and Hematology tests annually.